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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/592,914

09/10/2008

Xiu-Min Li

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24280 7590 01/30/2009  
CHOATE, HALL & STEWART LLP  
TWO INTERNATIONAL PLACE  
BOSTON, MA 02110

EXAMINER

HOFFMAN, SUSAN COE

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

01/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/592,914	<b>Applicant(s)</b> LI ET AL.	
	<b>Examiner</b> Susan Coe Hoffman	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. The preliminary amendment has been received and entered.
2. Claims 1-15 are currently pending.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on pages 9 and 20. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 4, 12, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lessening the severity of food allergies or anaphylactic shock, does not reasonably provide enablement for the prevention of food allergies or anaphylactic shock. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative

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skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition and method for preventing food allergies or anaphylactic shock. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent food allergies or anaphylactic shock for all potential causes of food allergies or anaphylactic shock. In addition, the art teaches that the only currently accepted means for complete prevention of food allergies or anaphylactic shock prevention is avoidance of allergens. The art does not teach that any pharmaceutical products are acknowledged as being useful in complete prevention of food allergies or anaphylactic shock (see Burks (Expert Opin. Pharmacother. (2008), vol. 9, no. 9, pp. 1145-52, specifically pages 1145 and 1150) and El-Shanawany (Clinical and Experimental Immunology (2008) vol. 153, pp. 1-9, specifically page 6)). Thus, since applicant's specification does not show prevention of food allergies or anaphylactic shock and the art acknowledges that pharmaceuticals useful for complete prevention are not currently available, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of food allergies or anaphylactic shock.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson (WO 01/66122).

Applicant's claims are drawn to a composition which comprises an herbal mixture which consists of Ling-Zhi, Wu Mei, Chuan Jiao, Huang Lian, Huang Bai, Gan Jiang, Gui Zhi, Ren Shen and Dang Gui. The claims are also drawn to a method of treating or lessening the severity of food allergies or anaphylactic shock using this composition. Applicant's specification defines Ling-Zhi as *Ganoderma Lucidum*, Wu Mei as *Fructus Pruni Mume*, Chuan Jiao as *Pericarpium Zanthoxyli Bungeani*, Huang Lian as *Rhizoma Coptidis*, Huang Bai as *Cortex Phellodendri*, Gan Jiang as *Rhizoma Zingiberis Officinalis*, Gui Zhi as *Ramulus Cinnamomi Cassiae*, Ren Shen as *Radix Ginseng*, and Dang Gui as *Radix Angelicae Sinensis* (see page 16 - Table 1).

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Sampson teaches using an herbal composition to treat or lessen the severity of allergies including food allergies. The reference teaches using the herbal composition to protect against anaphylactic reactions to peanuts (see page 38, line 1 and page 65, Example 4). The herbal composition is used in combination with corticosteroids, anti-histamines, adjuvants, carriers, and excipients (see page 7, lines 8-13 and pages 30, 31, 33 and 34). The reference specifically claims that the herbal composition contains *Ganoderma lucidum* (Ling Zhi) and one other herb selected from a group which contains *Fructus Pruni Mume* (Wu Mei), *Pericarpium Zanthoxyli Bungeani* (Chuan Jiao), *Rhizoma Coptidis* (Huang Lian), *Cortex Phellodendri* (Huang Bai), *Rhizoma Zingiberis Officinalis* (Gan Jiang), *Ramulus Cinnamomi Cassiae* (Gui Zhi), *Radix Ginseng* (Ren Shen), and *Radix Angelicae Sinensis* (Dang Gui) (see claim 4). Page 6, lines 9-16 of the reference also teaches that the composition can contain one or more of these ingredients. Thus, the reference specifically encompasses a composition which consists of the same herbal ingredients as taught by applicant. Therefore, despite the fact that the reference does not specifically teach a single embodiment where the herbal composition consists of the same ingredients as claimed, an artisan of ordinary skill would be motivated to select between the ingredients taught by Sampson because Sampson does not teach that all of the herbal ingredients are required. This selection would lead to the composition as claimed by applicant because the reference specifically teaches that each of these ingredients is known to be useful in treating allergies. It is considered to be *prima facie* obvious to combine together two or more ingredients into a single composition when the prior art teaches that each of the individual ingredients is known to be useful for the same purpose (see MPEP section 2144.06).

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5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson as applied to claims 1-7, 10-15 above, and further in view of prior art admitted by applicant in the specification.

The teachings of Sampson are discussed above. The reference does not specifically teach including epinephrine or a bronchodilator in the composition. However, applicant's specification admits that it was known in the art at the time of the invention to use epinephrine and bronchodilators to treat food allergies (see paragraph 125). Thus, an artisan of ordinary skill would be motivated to use these ingredients in combination with the herbal composition for treating food allergies taught by the reference. As discussed above, it is considered to be *prima facie* obvious to combine together two or more ingredients into a single composition when the prior art teaches that each of the individual ingredients is known to be useful for the same purpose (see MPEP section 2144.06).

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/  
Primary Examiner, Art Unit 1655